

Instructions for use
HIGH SPEED MICROMOTOR
SMALL LARGE AND INTRA 80K




Please read carefully and keep this copy for further use






**HIGH SPEED MICROMOTOR SMALL
LARGE AND INTRA-80K(EN)**

1. TYPE

Sterilisable brushless micromotor.

2. SYMBOLS USED

 1639	CE Marking with the number of the notified body.
Rx Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	CAUTION! Refer to the accompanying documents
	Consult the accompanying documents

	Materials to be recycled The disposal and/or recycling of materials must be performed in accordance with the directives and the legislation in force.
	Sterilizable in autoclave up to the specified temperature
	Cleaning in machine authorized
	Manufacturer
	Coupling ring opening direction

3. INTENDED USE

The High speed micromotors small 20363033, large 20362033 and INTRA-80K 20261033 are active medical devices intended to convert electrical energy to mechanically drive handpieces and craniotome for cutting and shaping bone.

Rx Only

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4. INDICATION FOR USE

Product intended for professional use. The high speed micromotors small 20363033, large 20362033 and INTRA-80K 20261033 used in conjunction with high speed handpieces and craniotome and INTRA handpieces have been designed for cutting and shaping bones as part of surgical operations in the areas of ENT, head and neck, neuro and spine surgery such as otorhinolaryngology, maxillofacial surgery, spine and cranium surgical operation.

5. CONTRAINDICATION

None currently known.

6. PRECAUTIONS - WARNINGS

6.1. Warnings, Precautions for use

For additional information, please contact KARL STORZ at the address indicated on the first page of this document.



CAUTION

Use adequate irrigation and avoid excessive pressure on the tool. The use of a tool without irrigation and with excessive pressure may cause an inordinate amount of heat buildup

resulting in a thermal injury to tissue. See tools instruction for use for further information.



CAUTION

Do not use this device in the presence of a flammable anesthetics. Avoid potential ignition or explosion of gases.

The device and its accessories should be used only by duly trained and competent medical personnel, in particular in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and the present user manual. According to these measures, the user has the following obligations:

- To only use devices that are in perfect working condition. In the event of irregular operation, excessive vibrations, abnormal overheating or other signs suggesting malfunctioning of the device, work must be suspended immediately. In this case, contact a repair center approved by the legal manufacturer via KARL STORZ.
- Make sure that the device is used only for the purpose for which it is intended. Protect yourself, patients and third parties from all danger and avoid contamination by the product.

The device and its accessories are designed solely for medical treatment. Any use that does not comply with its intended use is unauthorized and may prove dangerous. This medical device complies with European legal provisions in force.

Use only original maintenance products, accessories and/or spare parts approved by the legal manufacturer. The use of other products, accessories or parts could void the guarantee and/or endanger the patient or the operator.

6.2. Environmental protection and indications for device disposal



This equipment must be recycled. The disposal and/or recycling of materials must be performed in accordance with the directives and the legislation in force. The user can

return the device to their distributor or directly call a firm certified to treat and recover this type of equipment (European directive 2012/19/EU).

7. TECHNICAL DATA

Environmental conditions:

Work	Temperature:	+10°C to +30°C (+50°F to +86°F)
	Relative humidity:	20% to 80%, including condensation
	Atmospheric pressure:	700 hPa to 1060 hPa
Transport	Temperature:	-25°C to +70°C (-13°F to +158°F)
	Relative humidity:	10% to 100%, including condensation
	Atmospheric pressure:	500 hPa to 1060 hPa
Storage	Temperature:	+10°C to +30°C (+50°F to +86°F)
	Relative humidity:	20% to 80%, including condensation
	Atmospheric pressure:	500 hPa to 1060 hPa

Type:

- High speed micromotor small 20363033: Direct current, brushless and sensorless.
- High speed micromotor large 20362033 and Intra-80K 20261033 micromotor: Direct current, brushless and sensorless, self-ventilated.

Coupling:

- High speed micromotor small 20363033 and large 20362033: high speed coupling
- INTRA-80K micromotor 20261033: E- Type as per ISO 3964, type 1, long

Maximum Rotation speed:
80'000 rpm

Noise level:

As per ISO 11498: < 62 dBA at 45 cm.

Size / Weight (without cable and without handpiece):

Micro-motor reference	Designation	Diameter including coupling (mm)	Length (mm)	Weight (g)
20362033	High-Speed Micromotor, large	23	77	115
20363033	High-Speed Micromotor, small	17	74	80
20261033	INTRA Micromotor-80k	21	100	120

Period of operation:



CAUTION

To avoid overheating leading to burns (temperatures between 41°C (106°F) and 48°C (118°F) on the outer surface of the micromotor), the following rules must be respected:

1. Limit the maximum speed of rotation according to the bur diameter as indicated on the packaging and/or in the present operating instructions.
2. Do not exceed the maximum permitted speed of rotation for the handpiece or rotary instrument.
3. Sufficient irrigation is recommended.
4. Duty cycle:

High speed micromotor small 20363033: for normal operating temperature room (typically 20°C) the micromotor is rated for 10s ON, 10s OFF. For an operating room at 30°C, the micromotor is rated for 30s ON, 2 min. OFF at maximum speed.

High speed micromotor large 20362033 and INTRA-80K micromotor 20261033: for normal operating room temperatures (typically 20°C), the micromotor are rated for continuous operation at

maximum speed. For an operating room at 30°C, the micromotor is rated for 30s ON, 2 min. OFF at maximum speed.

Medical class:

Ila as per 93/42 EEC directive.

Micromotor torque:

- High speed micromotor small 20363033: 25 mNm.
- High speed micromotor large 20362033: 45 mNm.
- INTRA-80K micromotor 20261033: Max. 40 mNm.

For further information concerning microsurgery instruments and their accessories, please contact your KARL STORZ local distributor or consult our www.karlstorz.com.

8. USE

8.1. Type of coupling

INTRA as per ISO 3964, type 1, long for the INTRA-80K 20261033 micromotor; KARL STORZ coupling for the High speed micromotor small 20363033 and large 20362033.

8.2. Handpiece insertion and removal for high speed micromotor small 20363033 and large 20362033

1. Insert the handpiece on the micromotor nose and rotate it to ensure correct coupling.
2. Connect the irrigation line to the handpiece as far as it will go.
3. Insert the irrigation line into the openings of the fixing flanges previously laid on the power cable.
4. To remove the handpiece, pull the micromotor coupling ring back and remove the handpiece.

8.3. Micromotor cable connection

Before connecting the specific micromotor cable, check the cleanliness of the rear of the micromotor and the cable plug.

1. Present the micromotor in correct alignment (align the cable reference with the reference on the micromotor).
2. Insert the plastic connector in position.
3. Tighten the connector nut as far as possible.
4. Before use, run the micromotor at moderate speed for a few seconds to distribute and remove excess lubricant.

9. CLEANING / INSPECTION / STERILIZATION

CAUTION

Do not place the micromotor in an ultrasonic bath.

CAUTION

Never submerge the micromotor in disinfection solutions or physiological salt water solutions (NaCl solution), as prolonged contact may cause corrosion.

CAUTION

To avoid water staying between the cable and the micromotor always hold/place the micromotor with the front end down (minimum 45°) during the entire cleaning process.

CAUTION

Chemical disinfection of the motors is not recommended due to possible negative effects on the lifetime of the devices and possible residues of disinfectants.

CAUTION

These devices are delivered "non-sterile".

Before use please comply with these instructions.

Precautions for use:

Hospital procedures must be followed.

Hospital personnel working with contaminated or potentially contaminated medical instruments must comply with universal precautions.

Pointed and sharp instruments should be handled with great care.

Agents required for cleaning:

• Detergents

The cleaning of the micromotor has been validated using an enzymatic pH neutral detergent (Enzoi®). An alkaline detergent might reduce the lifetime of the device.

Detergents should be used at the concentration, temperature and for the duration recommended by the detergent's manufacturer.

CAUTION

Do not use detergents that are corrosive or contain chlorine, acetone or bleach, aldehydic products or alcohols.

• Lubricant:

Exclusively use "Lubrifluid" from Bien-Air Surgery SA.

• Brush / cleaning gun

Brushes should be non-aggressive to avoid damaging the device. Preferably use nylon brushes with flexible or soft bristles. Use the cleaning gun with the appropriate nozzles for the various ducts.

If you have any additional questions regarding reprocessing procedures, instructions for reusable devices etc., please contact KARL STORZ. Contact information can be found on the first page of this instructions.

Before use, please comply with the present section:

- Clean, lubricate and sterilize the micromotor before first use.
- Clean, lubricate and sterilize the micromotor before each further use.
- After each use, clean and sterilize the micromotor as quickly as possible.

9.1. Point of Use cleaning:

CAUTION

Initial cleaning should be performed at the point of use and as soon as possible after the completion of the surgical procedure.



CAUTION

Point of use cleaning must be followed by manual or automatic cleaning.

This operation is important in order to facilitate subsequent cleaning stages (it prevents dirt from drying and sticking to the equipment).

As soon as you have finished using the device, proceed as follows:

- Disconnect the power cables from the control unit
- Separate all components: separate the handpiece from the motors, except the motor cables which should remain connected to the micromotor.
- Rub the outside surface of the device with non-woven towelettes (pre-soaked in water).
- Ensure that the instruments do not dry before manual or automatic cleaning by wrapping them in non-woven towelettes (pre-soaked in water).
- Manual or automatic cleaning must be done max 4h after the point of use.

9.2. Manual cleaning

Thoroughly rinse the micromotor and its cable under running tap water as follows:

- Rinse the micromotor including the first 10cm of the cable under running tap water (cold, max 20°C / 68°F) and brush with nylon soft bristles for at least 30 seconds. Continue brushing until soil is no longer visible.
- Make sure water goes through all the ventilation openings (if any).
- Rinse the coupling mechanism of the High speed micromotor small 20363033 / large 20362033 under running tap water (cold, max 20°C / 68°F) for at least 10 seconds while pulling back and rotating the locking ring of the coupling mechanism at least 3 times.
- Rinse the entire cable under running tap water (cold, max 20°C / 68°F) and wipe with a wet non-woven towelette until soil is no longer visible.

Thoroughly wash the micromotor and its cable with an enzymatic neutral pH detergent (for example Enzol[®]) solution as follows:

- Rub the entire cable with detergent impregnated non-woven wipes, moving back and forth.
- Wash the micromotor by pouring detergent solution. Pull and rotate the locking ring of the high speed micromotor small 20363033 / large 20362033 at least 3 times. Then, with a nylon soft bristles brush, brush the outside surfaces including the first 10cm of the cable with a soaked brush (especially in the corner, edges and openings) for at least 30 seconds. Continue brushing until soil is no longer visible.
- Wash the coupling mechanism of the high speed micromotor small 20363033 / large 20362033, then pull and hold it while brushing with nylon soft bristles brush around the whole circumference twice.

Thoroughly rinse the micromotor and its cable under running tap water as follows:

- Rinse the whole cable for at least 30 seconds.
- Rinse the device for at least 30 seconds. Make sure water goes through all the ventilation openings (if any).
- Rinse the coupling mechanism of the High speed micromotor small 20363033 / large 20362033 under running tap water (cold, max 20°C / 68°F) for at least 10 seconds while pulling back and rotating the locking ring of the coupling mechanism at least 3 times.

Drying:

- Dry the micromotor and the power cable by wiping with a clean and dry non-woven towelette.
- If the attachment is not immediately sterilized, perform dynamic drying under ventilation, at about ~90°C (194°F), for a minimum of 25 minutes.

Or

9.3. Automatic cleaning

Pre-cleaning:

- Rinse the micromotor including the first 10cm of the cable under running tap water (cold, max 20°C / 68°F) and brush with nylon soft bristles for at least 30 seconds on the outside surfaces. Continue brushing until soil is no longer visible.
- Make sure water goes through all the ventilation openings (if any).
- Rinse the coupling mechanism of the high speed micromotor small 20363033 / large 20362033 under running tap water (cold, max 20°C / 68°F) for at least 10 seconds while pulling back and rotating the locking ring of the coupling mechanism at least 3 times. Brush the coupling mechanism with nylon soft bristles for at least 15 seconds, continue brushing until soil is no longer visible.
- Rinse the entire cable under running tap water (cold, max 20°C / 68°F) and wipe with a wet non-woven towelette until soil is no longer visible.
- Pre-cleaning has to be directly followed by final automated cleaning

Automatic cleaning:

Insert the cap on the micromotor (only for High speed micromotor small 20363033). Place the micromotor with its cable in the appropriate washer/disinfector basket and treat via a standard instrument washer/disinfector cycle (place the micromotor with the tip downward minimum angle 45°).

Use exclusively a validated washer / disinfector (ISO15883).

This product has been validated with an automated cycle consisting of the following stages:

Pre-wash:

4 minutes cold tap water.

Washing:

With enzymatic neutral pH detergent and hot tap water, 55°C to 66°C (131°F to 149°F), for 10 minutes.

Apruošimas automatinėje plovyklėje.
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Rinsing¹:

Hot tap water for 3 minutes.

Thermal disinfection by rinsing:

Operator is responsible for the implemented value A0 according A0 concept described in EN ISO 15883 (For example, A0 600 90°C (194°F) /1min.).

Ventilated dynamic drying:

Approx. 90°C (194°F), for at least 25 minutes.

Remove the cap after washing (only for High speed micromotor small 20363033).

Comments:

- Comply with the washer/disinfector loading instructions provided by the equipment's manufacturer.
- Make sure that all instruments have been correctly attached to the baskets.
- Wind up the cable correctly and without any tension (minimum inner diameter 8 cm).
- Make sure that the instruments do not touch one another and that internal canals are properly rinsed.
- Remove the instruments from the washer or disinfector immediately after the machine stops and quickly lubricate and sterilize to avoid corrosion.

9.4. Inspection, lubrication and testing

Carefully inspect each part to make sure that all visible contamination and moisture has been removed. Where there is contamination, repeat the full cleaning process. Where there is moisture, use the airgun to dry it.

After each cleaning operation and before each sterilization, lubricate the micromotor with "Lubrifluid" from Bien-Air Surgery SA as follows:

- Pull the high speed micromotor small 20363033 / large 20362033 coupling and spray on it from the side with "Lubrifluid" spray for approx. 0.1 seconds to lubricate the moving parts of the coupling system including the balls.

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20362033 coupling. It must always return to its initial position.

No lubrication is required on the INTRA-80K micromotor with ISO3964 coupling. NOTE: The micromotor ball bearings have lifetime grease and do not require additional lubrication.

Check the device including its cable and connectors for any visible signs of deterioration or damage.

Packing for sterilization:

Separate packing: Immediately insert the micromotor in individual wrapping, such as a paper/plastic pouch or sterilization wrap for steam sterilization.

Make sure that the cable does not touch the sides of the sterilizer.

Or

Pack in stiff boxes and trays with defined, pre-configured lids and apertures and wrap the stiff boxes or tray.

In the USA, FDA approved sterilization wraps, pouches or containers must be used.

9.5. Sterilization

Sterilization by vacuum steam is recommended. The following sterilization parameters, using a Pre-Vac cycle, have been validated by the legal manufacturer to provide a sterility assurance level (SAL) of 10^{-6} .

Only legally marketed, FDA cleared sterilizers, sterilization wrap/pouches, biological indicators etc. should be used by the end-user for packaging terminally sterilized devices.

of the coupling
times the high
63033 / large

Temperature	132°C (270°F)	134°C ² (273°F)	134°C ² (273°F)	135°C (275°F)
Time	4 Min.	3 Min.	18 Min. ¹	3 Min.
Minimum drying time	30 Min ³			

¹ Parameters recommended by the World Health Organization for treating instruments in the event of contamination by Non-Conventional Transmissible Agents (NCTA).

² Not for users in US healthcare facilities.

³ Refer to sterilizer manufacturer recommendations for drying times per load configuration.

After sterilization, let the device cool down to room temperature without forced cooling.

For USA only: Use sterilization cycles consistent with the cycle specifications in ANSI/AAMI ST97 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities".

Since no reprocessing methods have been validated for removing transmissible spongiform encephalopathy (TSE) agents from medical devices, this device should not be used for patients with known or suspected TSE agent disease, including CJD and vCJD. The legal manufacturer recommends incinerating devices that have come into direct contact with patients suspected of or confirmed as having TSE/CJD.

The sterilizer manufacturer instructions concerning operation and load configuration should be complied with explicitly.

⚠ CAUTION

Do not exceed a temperature of 138°C (280°F).

⚠ CAUTION

Never rinse instruments in cold water to cool them.

9.6. Storage

The legal manufacturer strongly advises storing only sterilized devices to reduce the risk of corrosion.

Ambient conditions for storage after sterilization:

- Store the equipment in a clean, dry place at an ambient temperature (10–30°C (50–86°F), 20–80% humidity).
- Do not expose the equipment to direct sunlight.
- Do not expose the equipment to permanent X-ray irradiation.
- Do not store the equipment in places that could be subject to liquid splashes.
- Do not store the equipment in the following ambient conditions: - Dust - Saline or sulfurous atmosphere
- Do not store the equipment in a location where there is a risk of the release of flammable gases.

Shelf life of sterilized instruments:

The shelf life of stored sterilized instruments depends on the type of packaging used and the storage conditions (refer to the DIN 58953 standard, section 9, or existing local regulations).

10. MAINTENANCE

No small 20363033 / large 20362033 / INTRA-80K 20261033 micromotor components are to be changed by the user. Never disassemble the micromotor.

For all servicing and repairs, we recommend that you contact your dealer or KARL STORZ directly.

The legal manufacturer invites users to have their dynamic instruments checked or serviced once to twice a year depending on usage frequency.

Hygiene

For the safety of the repair center's personnel, the instrument should be fully cleaned and sterilized before being returned for repair. If that proves impossible, for example because disinfection or

sterilization would make the instrument completely unusable, clean the instrument as carefully as possible and mark it accordingly to indicate that it has not been decontaminated.

11. MALFUNCTIONS AND ERRORS

Use the table below to solve any problems encountered. If the problem cannot be solved, stop using the product and contact a repair center approved by the legal manufacturer.

Problem	Solution
The micromotor is not working	Make sure that the cable is properly connected to the micromotor and the control unit. Make sure that the control unit is turned on and micromotor is selected. Check the condition of the micromotor power cable (broken contact or severed cable).
The micromotor cuts out completely	Check the state of connections and cable. A part may be broken, return the micromotor to the after-sales service.
Abnormal heating of the micromotor	Check handpiece function. If the operating and maintenance instructions of the micromotor have been observed, return the micromotor to after sales-service because the bearings are probably worn.
The instrument does not stay fixed on the micromotor	Check that the attachment ring of the INTRA-80K 20261033 micromotor is correctly in position and not damaged.

Check that the balls and that the coupling rings of the high speed micromotor small 20363033 / large 20362033 are well placed and that they are not damaged.

